



1303 '99 MR 23 P2:16

March 15, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Herbal Energy Complex: [It] promotes energy and endurance. Ginseng enhances the body's ability to utilize oxygen, helping to vitalize and rejuvenate the entire body. Sundown Herbal Energy Complex combines Ginseng with a blend of other beneficial herbs to support vitality. To further promote sustained energy levels, take Sundown Ginseng Complex with Sundown B-Complex and Sundown Co Q-10. B-vitamins are essential for promoting sustained energy levels throughout the day. Co Q-10 also plays a critical role in the production of energy in every cell of the body. Sundown Herbal Complex formulas are carefully selected herbal combinations that naturally promote well-being. In Sundown Herbal Energy Complex, Ginseng is complemented with Bee Pollen, Cayenne Pepper and Ginger to naturally support energy, endurance and vitality.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Urbanah Shun Dinka Deborah Shur Trinker

Vice President of Regulatory Affairs and Assistant General Counsel

Enclosure